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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/737,457	03/12/97	CARDY	D 960670.ORI

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EXAMINER	
EWOLDT,G	
ART UNIT	**PAPER NUMBER**
1644	30

DATE MAILED: 10/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/737,457	Cardy et al.
Examiner	**Art Unit**
G. R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 25, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-3, 5-12, and 14-24* is/are pending in the application.

4a) Of the above, claim(s) *24* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3, 5-12, and 14-23* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. The request filed on 5/25/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/737,457 is acceptable and a CPA has been established. An action on the CPA follows.

2. A species election was required under 35 U.S.C. § 121 in the parent application, as set forth in Paper No. 8, mailed 8/04/98.

Applicant elected an anti-MHC binding portion, a p53 effector portion, and an HIV tat translocation portion, with traverse. This restriction requirement is hereby reiterated.

The requirement is still deemed proper for the reasons of record as set forth in Paper No. 8, mailed 8/04/98, and is therefore made FINAL.

3. Claim 24 stands withdrawn from further consideration by the examiner as being drawn to non-elected species.

Claims 1-3, 5-12, and 14-23 are being acted upon.

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. As noted in **three** previous actions/letters, the peptide sequences on page 11, line 5, page 12, line 1, and page 13, line 10 of the specification must be brought into sequence compliance. Said compliance includes the identification of said sequences in the specification by SEQ ID NO:.

5. In view of Applicant's amendment and response, filed 5/25/01, only the following rejections remain.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 20-23 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth previously in Paper No. 19, mailed 6/13/00.

8. Applicant's arguments, filed 5/25/01, have been fully considered but have not been found convincing. Applicant appears to argue that the amending of Claim 21 to recite a method of modulating an immune response in "a target cell" rather than in a subject (*in vivo*) obviates the previous rejection. Applicant further argues that the claimed polypeptide does not provide a treatment for conditions requiring immunostimulation and immunosuppression at the same time. Applicant further argues that Examples 1-4 and 5-8 disclose methods of treatment for conditions requiring immunostimulation while Examples 6 and 9 disclose guidance for the treatment of conditions in need of immunosuppression. It is the Examiner's position that even as amended, the specification can not sufficiently support the breadth of the claims, particularly regarding a) the vaccine of Claim 20 and b) methods of "modulating" which would encompass immunosuppression. Regarding a vaccine, clearly the invention is drawn to a polypeptide comprising *in vivo* use, as such, the invention stands rejected for the reasons of record. Regarding methods of modulating, whether in a subject (as previously claimed), or in a target cell (as instantly claimed), the specification is insufficient to support the entire breadth of the claims as set forth previously. It is noted that Applicant asserts that the specification discloses guidance for the treatment of conditions in need of immunosuppression, however, said "guidance" consists entirely of two prophetic examples indicating that the claimed polypeptide could be administered to a patient. Said "guidance" is insufficient to support the claimed invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-3, 5-12, and 14-23, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Casten et al. (1988, of record) in view of Fawell et al. (1994, of record), and Noguchi et al. (1994, of record), for the reasons set forth in Paper No. 19, mailed 6/13/00.

11. Applicant's arguments, filed 5/25/01, have been fully considered but have not been found convincing. Applicant "questions" the Examiner's interpretation that the Casten et al. reference teaches "the internalization and subsequent processing of the antibody conjugate." Applicant appears to misunderstand the rejection. Paragraph 14 of the action mailed 6/13/00 states that the Casten et al. reference teaches a polypeptide comprising a binding portion and an effector portion. As should be clear from the previous actions, it is the Examiner's position that the polypeptide of the prior art inherently possesses the properties of the polypeptide of the instant claims. However, as the polypeptide of the prior art does not specifically comprise a tat portion and a p53 portion, the reference teaching the polypeptide of the prior art was used as a reference in a 103(a) obviousness type rejection and not a 102(b) rejection. Further, it is the Examiner's position that the combination of "portions" (more scientifically referred to as domains) of the instant claims would be obvious for the reasons of record as set forth previously. In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

12. The following are New Grounds of Rejection.

13. Claims 1, 5-12, and 14-23 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the

disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "A chimaeric polypeptide comprising ... a signal from another source,"

B) "A method of modulating the immune response of a target cell, comprising administering to the target cell ..."

Applicant's amendment, filed 5/25/01, fails to assert that no new matter has been added, and no support for the amended claims has been found in the specification.

Applicant is advised that should "from another source" be removed from Claim 1 so that the claims again recite the polypeptide of the previous claims, all rejections previously made to said claims would be reintroduced as new rejections comprising new issues.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 6-7, 9, and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) as generally used in the immunological arts, an "immune response" is considered to be a response by an organism and not the response of an individual cell, thus, it is unclear just what an immune response of a cell comprises,

B) "subject" in Claim 23 has no antecedent basis in Claim 22 or Claim 21,

C) the terms "modulate" or "immunomodulate" have not been defined in the specification; as said terms might encompass responses ranging from increased or decreased production of a cytokine to apoptosis, they are considered vague and indefinite, absent a specific definition.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
October 29, 2001

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600